

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

FERRING B.V.,

Plaintiff,

vs.

WATSON LABORATORIES, INC. - (FL) et al.,

Defendants.

3:11-cv-00481-RCJ-VPC

ORDER

FERRING B.V.,

Plaintiff,

vs.

APOTEX, INC. et al.,

Defendants.

3:11-cv-00485-RCJ-VPC

ORDER

FERRING B.V.,

Plaintiff,

vs.

WATSON PHARMACEUTICALS, INC. et al.,

Defendants.

3:11-cv-00853-RCJ-VPC

ORDER

FERRING B.V.,

Plaintiff,

vs.

APOTEX, INC. et al.,

Defendants.

3:11-cv-00854-RCJ-VPC

ORDER

1 These four consolidated cases arise out of Defendants' application with the Food and
2 Drug Administration ("FDA") to manufacture and sell generic versions of a patented drug.
3 Pending before the Court are sixteen motions to seal, three motions for leave to file a reply, and
4 eight motions in limine.

5 **I. FACTS AND PROCEDURAL HISTORY**

6 These cases arise out of the alleged infringement of Plaintiff Ferring B.V.'s ("Ferring")
7 U.S. Patent No. 7,947,739 for tranexamic acid tablets sold under the trademark Lysteda® (the
8 "'739 Patent" or "Tablet Patent"), (*see* Compl. ¶¶ 13–17, July 7, 2011, ECF No. 1; Compl. ¶¶
9 9–13, July 8, 2011, ECF No. 1 in Case No. 3:11-cv-00485), and the alleged infringement of
10 Ferring's U.S. Patent No. 8,022,106 for tranexamic acid formulations and methods of treating
11 menorrhagia therewith (the "'106 Patent" or "Formulas and Treatment Patent"), (*see* Compl. ¶¶
12 13–17, Nov. 25, 2011, ECF No. 1 in Case No. 3:11-cv-00853; Compl. ¶¶ 9–13, Nov. 25, 2011,
13 ECF No. 1 in Case No. 3:11-cv-00854).¹ In the '481 and '485 Cases, respectively, Ferring sued
14 several Watson Labs entities (collectively, "Watson Defendants") and several Apotex entities
15 (collectively, "Apotex Defendants") in this Court for infringing the '739 Patent. In the '853 and
16 '854 Cases, respectively, Ferring sued several Watson Defendants and several Apotex
17 Defendants in this Court for infringing the '106 Patent.

18 The Court consolidated the four cases, with the '481 Case as the lead case. It also granted
19 motions to dismiss the counterclaims for invalidity and to strike affirmative defenses for
20 invalidity in the '481 and '854 Cases, with leave to amend. The Court ruled that affirmative
21 defenses must specify a distinct legal theory of invalidity under Rule 8(c) but need not be pled
22 according to the *Iqbal* plausibility standard, as the counterclaims must be under Rule 8(a).
23 Watson Defendants and Apotex Defendants amended their answers and counterclaims,

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25 ¹Unless otherwise noted, the docket numbers in this document refer to Case No. 3:11-cv-00481.

1 accordingly. (See ECF Nos. 93, 94). Apotex Defendants later further amended its answer and
2 counterclaim. The Court has denied motions to dismiss the amended counterclaims for
3 invalidity. The Court has held a *Markman* hearing and issued a claim construction order.

4 **II. LEGAL STANDARDS**

5 A motion in limine is a procedural device to obtain an early and preliminary ruling on the
6 admissibility of evidence. Black's Law Dictionary defines it as "[a] pretrial request that certain
7 inadmissible evidence not be referred to or offered at trial. Typically, a party makes this motion
8 when it believes that mere mention of the evidence during trial would be highly prejudicial and
9 could not be remedied by an instruction to disregard." *Black's Law Dictionary* 1109 (9th ed.
10 2009). Although the Federal Rules of Evidence do not explicitly authorize a motion in limine,
11 the Supreme Court has held that trial judges are authorized to rule on motions in limine pursuant
12 to their authority to manage trials. See *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984) (citing
13 Fed. R. Evid. 103(c) (providing that trial should be conducted so as to "prevent inadmissible
14 evidence from being suggested to the jury by any means"))).

15 A motion in limine is a request for the court's guidance concerning an evidentiary
16 question. See *Wilson v. Williams*, 182 F.3d 562, 570 (7th Cir. 1999). Judges have broad
17 discretion when ruling on motions in limine. See *Jenkins v. Chrysler Motors Corp.*, 316 F.3d
18 663, 664 (7th Cir. 2002). However, a motion in limine should not be used to resolve factual
19 disputes or weigh evidence. See *C&E Servs., Inc., v. Ashland, Inc.*, 539 F. Supp. 2d 316, 323
20 (D.D.C. 2008). To exclude evidence on a motion in limine "the evidence must be inadmissible
21 on all potential grounds." *E.g., Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D.
22 Ohio 2004). "Unless evidence meets this high standard, evidentiary rulings should be deferred
23 until trial so that questions of foundation, relevancy and potential prejudice may be resolved in
24 proper context." *Hawthorne Partners v. AT&T Tech., Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill.
25 1993). This is because although rulings on motions in limine may save "time, costs, effort and

1 preparation, a court is almost always better situated during the actual trial to assess the value and
2 utility of evidence.” *Wilkins v. Kmart Corp.*, 487 F. Supp. 2d 1216, 1219 (D. Kan. 2007).

3 In limine rulings are provisional. Such “rulings are not binding on the trial judge [who]
4 may always change his mind during the course of a trial.” *Ohler v. United States*, 529 U.S. 753,
5 758 n.3 (2000); accord *Luce*, 469 U.S. at 41 (noting that in limine rulings are always subject to
6 change, especially if the evidence unfolds in an unanticipated manner). “Denial of a motion in
7 limine does not necessarily mean that all evidence contemplated by the motion will be admitted
8 to trial. Denial merely means that without the context of trial, the court is unable to determine
9 whether the evidence in question should be excluded.” *Ind. Ins. Co.*, 326 F. Supp. 2d at 846.

10 **III. ANALYSIS**

11 Before addressing the motions in limine, the Court will grant the sixteen motions for
12 leave to file those motions and related pleadings under seal. The Court in its discretion denies
13 the three motions to file replies to Defendants’ oppositions to Plaintiff’s motions in limine.
14 See Local R. 16-3(b). The Court has more than sufficient briefing before it to determine these
15 preliminary matters. The Court addresses the eight pending motions in limine below.

16 **A. Motion #355**

17 Watson Defendants ask the Court to exclude Ferring from adducing at trial Dr.
18 Williams’s opinions concerning the doctrine of equivalents. Watson Defendants ask the Court to
19 prevent Dr. Williams from testifying that the Patents cover the dissolution of tranexamic acid
20 dosages in media other than water, because the patents claim only water-based dissolution
21 profiles. Watson Defendants argue that Ferring would never have obtained the Patents but for
22 their representation to the USPTO that the patent applied only to water-based dissolution
23 profiles. Watson Defendants also note that Dr. Williams is a pharmaceutical expert, not a patent
24 lawyer, and that any proffered expert opinion on the infringement issue is outside the scope of his
25 expertise.

1 The Court grants the motion in part. Dr. Williams may not testify as to his opinions
2 concerning infringement or the breadth of the Patents. Even assuming Dr. Williams could be
3 qualified as a patent expert, the Court does not require his aid in construing claims. The Court
4 has construed the claims and will determine the claims, accordingly. But Ferring may argue
5 infringement based upon its perception of the doctrine of equivalents, so long as it does not
6 attempt to contradict the Court on the law. It is for the Court as fact-finder to determine if the
7 accused product infringes the claims as construed. Ferring may argue that it does, and Watson
8 Defendants may argue that it does not, based upon the evidence and the Court's instructions.

9 **B. Motion #356**

10 Watson Defendants ask the Court to exclude Dr. Lukes's testimony comparing side
11 effects of prior art to side effects of Ferring's Lysteda product. Watson Defendants argue that Dr.
12 Lukes: (1) fails to follow scientifically accepted methodology; (2) ignores evidence contrary to
13 her litigation position; and (3) ostensibly relies on patient hearsay, but provides no evidence to
14 support her claims.

15 The Court denies the motion. The first issue is based upon the long-overruled *Frye*
16 standard. *See Daubert v. Merrill Dow Pharms., Inc.*, 509 U.S. 579, 586–87 (1993) (noting that
17 Federal Rule of Evidence 401 governing the relevance of evidence as a general matter
18 superseded the former generally-accepted-methods test of *Frye v. United States*, 293 F. 1013
19 (D.C. 1923)). The Court will determine if Dr. Lukes's methods were reliable in the context of
20 her testimony at trial under *Daubert*. The second issue goes to the weight of the anticipated
21 testimony, which Watson Defendants can address via cross-examination, impeachment, rebuttal,
22 and argumentation. The third issue is similar to the second issue but also goes to the source of
23 Dr. Lukes's opinions. But, assuming she is qualified as an expert, the basis for an expert
24 witness's opinions need not be themselves admissible. *See Fed. R. Evid. 703* ("An expert may
25 base an opinion on facts or data in the case that the expert has been made aware of or personally

1 observed. If experts in the particular field would reasonably rely on those kinds of facts or data
2 in forming an opinion on the subject, they need not be admissible for the opinion to be
3 admitted.”). If Dr. Lukes’s testifies that she has been made aware of or personally heard patient
4 comments concerning the side effects of prior art drugs or the patented drugs, and if experts in
5 her field would rely on that type of information, then the evidence is admissible.

6 **C. Motion #357**

7 Watson Defendants ask the Court to exclude Ferring’s dissolution testing done at the
8 Pharmatek and SSCI labs because the testing was unreliable and/or “doctored” in the following
9 ways: (1) Ferring failed to deliver to either Watson Defendants or Ferring’s own expert, Dr.
10 Wilson, all results from Pharmatek’s testing, but only those results supporting Watson’s position;
11 (2) the same is true of testing results from SSCI; (3) Ferring used only test results based upon a
12 method (the “lobster trap” method) identified as inappropriate by its own expert, Dr. Koleng, and
13 did not use the results of the proper testing, which showed no infringement; (4) at Pharmatek,
14 testing was repeated on certain tablets, replacing the first samples tested with different tablets,
15 and only the replacement samples were found by Ferring to be infringing; (5) of the thirty batches
16 provided to Ferring, Ferring provided SSCI with samples from only a single batch and ignored
17 the results of its prior Pharmatek testing showing that one batch behaved significantly different
18 from all other batches tested; and (6) Ferring’s dissolution testing is unreliable and should be
19 excluded because the test results from Pharmatek did not follow scientific protocol—only two
20 tablets were tested, instead of the required six unit samples necessary for an accurate measure of
21 the dissolution characteristics of the batch sampled. The Court denies the motion. The
22 argumentation in the motion goes to the weight of the evidence and issues for cross-examination
23 of Ferring’s experts.

24 **D. Motion #360**

25 Apotex Defendants ask the Court to exclude as irrelevant any testimony by Dr. Williams

1 relying upon a construction of the term “about” as meaning plus or minus 10%, because the
2 Court ruled that the term means “approximately.” (See Claim Construction Order 19:14, Feb. 6,
3 2013, ECF No. 295). The motion is denied. Again, Dr. Williams may not testify as to whether
4 there has or has not been infringement, although he may testify as to fact relevant to that
5 determination. The Court will determine infringement as fact-finder according to its claim
6 construction.

7 **E. Motion #364**

8 Apotex Defendants ask the Court to exclude any testimony by Dr. Williams regarding
9 infringement based upon “single point” dissolution specifications, because the Patents are based
10 upon dissolution release rates based upon dissolution limitations as specified at two or more
11 points in time. The motion is denied for the same reasons Motion #360 is denied.

12 **F. Motion #366**

13 Plaintiff asks the Court to preclude Watson Defendants from relying upon a new claim
14 construction inconsistent with the Court’s *Markman* Order. The motion is denied. As the Court
15 has noted, the Court will rely upon the claim construction it has issued. The parties will not be
16 permitted to argue the law contrary to this construction, and the Court will not take testimony as
17 to the ultimate issue of infringement, but only as to fact relevant thereto. Testimony as to the
18 ultimate issue of infringement will be particularly unhelpful in this case, where it is clear all
19 parties wish to base such conclusions upon their own constructions of the claims inconsistent
20 with the Court’s authoritative construction. The Court will not revisit these claim construction
21 and summary judgment-type issues via motions in limine, which must be directed to specific
22 testimony that is inadmissible for specific reasons.

23 **G. Motion #369**

24 Ferring asks the Court to preclude Watson Defendants from offering testimony through
25 its rebuttal expert Dr. Maurin concerning the meaning of the term “about” or the prosecution

1 histories of the Patents, beyond what is in his disclosed expert report. Ferring argues that Dr.
2 Maurin refused to answer questions concerning these issues at his deposition, limiting his
3 answers to the statements in his rebuttal report. The Court has reviewed the objected-to portions
4 of deposition testimony. It appears the witness may have been attempting to evade answering the
5 question directly, i.e., whether the USP 27 included the word “about.” The Court makes no
6 determination at this point whether there was in fact an inappropriate refusal to answer. In any
7 case, the witness will not have this luxury at trial where he will face the immediate threat of
8 direct contempt if he refuses to answer questions put to him. But the potential evasion is not
9 enough to preclude Dr. Maurin from testifying upon the disputed issue at trial, because the
10 evasion was made simply to avoid making a harmful admission—it seems clear that Ferring’s
11 counsel knew what the answer was and simply wanted Dr. Maurin to admit it—not to conceal
12 evidence, which would be a more serious matter. There is therefore no prejudice to Ferring from
13 the witness’s failure to answer. These answer to the question will be clear at trial, and the fact of
14 the apparent evasion can be used for impeachment. And, as Watson Defendants note, this kind
15 of issue would have been more appropriately resolved via Rule 37. The Court denies the motion.

16 **H. Motion #372**

17 This motion is similar to Motion #366 and is denied for the same reasons.

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CONCLUSION

IT IS HEREBY ORDERED that the Motions to Seal (ECF Nos. 354, 359, 365, 368, 371, 378, 380, 383, 385, 387, 390, 392, 394, 396, 399, 401) are GRANTED. The documents requested to be sealed have already been filed under seal. No further action by the Clerk is required.

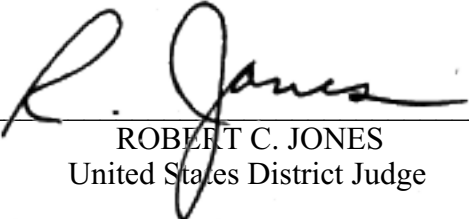
IT IS FURTHER ORDERED that the Motions for Leave to File Reply (ECF Nos. 395, 398, 400) are DENIED.

IT IS FURTHER ORDERED that the Motion in Limine (ECF No. 355) is GRANTED IN PART and DENIED IN PART.

IT IS FURTHER ORDERED that the Motions in Limine (ECF Nos. 356, 357, 360, 364, 366, 369, 372) are DENIED.

IT IS SO ORDERED.

Dated this 26th day of November, 2013.



ROBERT C. JONES
United States District Judge